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K04 2037



510(k) Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Kacy Arnold
Regulatory Specialist

Proprietary Name: M²a™ Magnum™ System

Common Name: Metallic Acetabular Articulation

Classification Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis (888.3330)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The M²a™ Magnum™ System is substantially equivalent to:

- K011110 M2a™ Acetabular System 38mm (Biomet)
- K984028 Bio-Moore Endo Heads (Biomet)
- K002106 New Bio-Moore Endo Head, Taper Adapter (Biomet)
- K031963 Conserve® Plus Spiked Shell and Conserve® Total 56mm Femoral Head (Wright Medical)
- K021249 Metal Transcend® Articulation System (Wright Medical)

Device Description:

The M²a™ Magnum™ System consists of a CoCrMo monolithic acetabular cup, which articulates with a CoCrMo modular head. The smaller femoral heads, sizes 38mm and 40mm, are a one-piece design with neck length variations ranging from -6mm to +12mm. The larger femoral heads, sizes 42mm to 60mm, are a modular design with neck length variations ranging from -6mm to +9mm, achieved through the use of a titanium adapter assembled with the modular head component at the time of surgery. The femoral heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral component.

Summary of Technologies: The M²a™ Magnum™ Hip System technological characteristics (material and design) are similar to predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

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